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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,292	08/08/2001	David R. Walt	A-67209-6 RMS DCF SRN	3460

7590

04/02/2003

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EXAMINER
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SANGHAVI, HEMANG

ART UNIT	PAPER NUMBER
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2874

DATE MAILED: 04/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/925,292

Applicant(s)

WALT ET AL.

Examiner

Hemang Sanghavi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 27 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 24-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

In response to the applicant's amendment received on December 27, 2002, all requested changes to the claims have been entered.

Applicant's arguments with respect to claims have been considered but are deemed to be moot in view of the new grounds of rejections. The previously applied rejections of claims 24-25 and 45 are withdrawn, as is the indicated allowability of claims 26-44 and 46-57. The following rejections are now applied as the result of further search. This action is not made final.

### ***Claim Objections***

Claims 32 and 66 are objected to because of the following informalities: In lines 1-2 of claim 32, the phrase "wherein said population of microspheres comprises at least a first and second subpopulation," should be deleted, since this limitation is claimed in claim 66 from which claim 32 depends from. In line 1 of claim 66, "method" should be changed to --composition--, since the composition is being claimed in claim 25. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pope (US 2002/0197456 A1, claiming a priority of continuing application filed on August 26, 1993).

Pope discloses a biochip comprising a substrate with discrete wells and a population of microspheres distributed in wells. Each well can have only one microsphere.

Pope fails to explicitly disclose a density of at least 100 discrete sites per 1 mm<sup>2</sup> and the population of microspheres includes a first and a second subpopulation.

However, in paragraph [0257] at page 17, Pope states that the microspheres could be placed in each well and attached with adhesive. Pope further teaches that the bioactive function of each array can be customized for a specific application through the selection of the microspheres to be placed in it. Also, the silica or glass substrate has capability of providing such large discrete sites. Providing an optimum number of sites on the substrate would require routine experimentation. Pope at paragraph [0258] further teaches that the key to the BioOptix chip is the ability to have a large plurality of sensels on a single chip of very small dimensions.

From collective teachings of Pope and routine experimentation, the ordinary artisan would have found optimum discrete sites (100 sites per 1 mm<sup>2</sup>) that can be formed on the substrate of Pope for the purpose of advantageously providing desired number of sensing array on the substrate.

The ordinary artisan would have found it obvious at the time of the invention to provide subpopulations of microspheres as taught by Pope for the advantageously customizing the biochip for a specific application.

As to claim 26, Pope discloses an optical fiber bundle substrate to which the microspheres are attached. See Fig. 4.

As to claim 27, Pope discloses the substrate is selected from the group consisting of silicon or glass. See Fig. 6 and paragraph [0262] at page 18.

As to claims 28 and 32, Pope fails to explicitly state that the microspheres of the first subpopulation are of different size than the microspheres of the second subpopulation.

However, as discussed above, Pope teaches that the microspheres that the bioactive function of each array can be customized for a specific application through the selection of the microspheres to be placed in it. Pope further teaches that the microspheres utilized can be porous or dense, organic or inorganic, depending upon the specific biological and/or chemical interaction being investigated.

From teachings of Pope, the ordinary artisan would have found it to be obvious at the time of the invention to select desired microspheres on each well of the substrate with different sizes (i.e., choosing different materials would inherently have different

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sizes) for the purpose of advantageously investigated desired and specific biological and/or chemical interaction.

As to claims 29-31, 40-43, 60-63, and 67, see paragraphs [0257] at page 17 and paragraph [0278] at page 18.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6,327,410. Although the conflicting claims are not identical, they are not patentably distinct from each other. The only difference between the claims of the instant application and the claims of U.S. Patent No. 6,327,410 is that the claims of the instant application claims additional limitation of "the site can have only a single microsphere".

The ordinary artisan would have found it obvious matter of design choice to provide desired number of microspheres to provide desired detection of biological or chemical agent.

**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Toledano discloses an immunoenzymatic detection device using microspheres.

Chee et al discloses substantially claimed invention, however this reference is not available as prior art due to its publication date.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemang Sanghavi whose telephone number is 703-305-3484. The examiner can normally be reached on Monday-Thursday (8:30 AM-6:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rodney Bovernick can be reached on 703-308-4819. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9318 for regular communications and 703-872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.



Hemang Sanghavi  
Primary Examiner  
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March 20, 2003